

REMARKS

Status of the Claims

After entry of the instant Amendment, claims 1-3 and 5-10 are pending in the present application. Claims 1 and 9 are independent.

Claim 4 has been cancelled without prejudice or disclaimer of the subject matter contained therein. Claims 1-3 and 5-10 have been amended. Support for amendments to the claims can at least be found in original claim 4, page 6, paragraph [0011] and page 7, paragraph [0015] of the Specification as filed. Thus, no new matter has been added by way of amendment to the claims.

Reconsideration of this application, as amended, is respectfully requested.

Priority under 35 U.S.C. § 119

Applicant thanks the Examiner for acknowledging Applicant's claim for foreign priority under 35 U.S.C. § 119. However, the Examiner states that certified copies of the Priority Documents have not been received.

The Examiner is respectfully requested to contact the International Bureau and request the Priority Document through the Digital Access Service (DAS) for Priority Documents.

Information Disclosure Citations

Applicant thanks the Examiner for considering the references cited in the Information Disclosure Statements filed December 15, 2005, September 1, 2006, November 21, 2007, and January 30, 2008, and for providing Applicant with initialed copies of the PTO-SB08 forms filed therewith.

Drawings

Applicant thanks the Examiner for indicating that the drawings are accepted.

Specification Objection

The Examiner has objected to the Specification for not referencing the international application to which the present application claims priority.

Applicant has amended the Specification to indicate that the present application is a National Stage Application under 35 U.S.C. § 371(c) of PCT Application No. PCT/JP2004/008025, filed June 9, 2004, which claims the priority of Japanese Patent Application No. 2003-173927 filed June 18, 2003, and Japanese Patent Application No. 2003-359158 filed October 20, 2003.

In view of the amendment to the Specification, reconsideration and withdrawal of this objection are respectfully requested.

Objections to Claim 8

The Examiner has objected to claim 8. Applicant has amended claim 8, as suggested by the Examiner at page 2 of the Office Action to obviate this objection. That is, Applicant has inserted the phrase "the hybrid plant" immediately after "producing" in line 1 of claim 8.

Applicant respectfully requests that the objection to claim 8 be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 3 and 7-10 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. This rejection is respectfully traversed.

In order to address this rejection, Applicant has amended claims 3 and 7-10 as suggested by the Examiner at pages 2-3 of the Office Action.

Applicant respectfully submits that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. § 102(b/e)

Claim 9 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Tang et al., "Cosegregation of single genes associated with fertility restoration and transcript processing of sorghum mitochondrial orf107 and urf209," Genetics, 1998, Vol. 150, No. 1, pp. 383-391 (hereinafter "Tang").

Claim 9 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Brown et al., U.S. Patent No. 7,314,971 (hereinafter "Brown").

Claims 1-2 and 7-10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mariani et al., U.S. Patent No. 6,046,382 (hereinafter "Mariani").

Applicant respectfully traverses these rejections of claims 1-2 and 7-10 under 35 U.S.C. § 102.

Each of Tang, Brown, and Mariani does not teach every element of the claimed invention. Specifically, none of the cited art references teaches a hybrid plant having two or more copies of a gametic fertility restorer gene at two or more gene loci, which do not have a complete linkage relationship. The unexpected results of having two or more copies of a gametic fertility restorer gene at two or more gene loci in the claimed hybrid plants will be discussed in greater detail below.

In view of the discussion above, Applicant respectfully requests that the rejections of claims 1-2 and 7-10 under 35 U.S.C. § 102 be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-4 and 7-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brown.

Claims 1-4 and 7-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanson et al., U.S. Patent No. 7,164,058 (hereinafter "Hanson") in view of Mariani and further in view of Schöffl et al., "An SAR sequence containing 395 bp DNA fragment mediates enhanced, gene-dosage-correlated expression of a chimaeric heat shock gene in transgenic tobacco plants," Transgenic Res., 1993, Vol. 2, No. 2, pp. 93-100 (hereinafter "Schöffl").

Further, claims 1-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanson, in view of Mohanty et al., "Agrobacterium-mediated high frequency transformation of an elite indica rice variety Pusa Basmati 1 and transmission of the transgenes to R2 progeny," Plant Science, 1999, Vol. 147, pp. 127-137 (hereinafter "Mohanty") and further in view of Akagi et al., "A unique sequence located downstream from the rice mitochondrial atp6 may cause male sterility," Curr Genet., 1994, Vol. 25, No. 1, pp. 52-58 (hereinafter "Akagi").

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanson, in view of Mohanty and further in view of Kazama et al., "A pentatricopeptide repeat-containing gene that promotes the processing of aberrant atp6 RNA of cytoplasmic male-sterile rice," FEBS Lett., 2003, Vol. 544, pp. 99-102 (hereinafter "Kazama").

Claim 4 has been cancelled and its rejection is therefore moot. Applicants respectfully traverse the rejections of claims 1-3 and 5-10 under 35 U.S.C. § 103(a).

The claimed hybrid plant that has two or more copies of a gametic fertility restorer gene at two or more gene loci that do not have a complete linkage relationship exhibits higher fertility compared to plants of the prior art.

At page 7, paragraph [0015] the present Specification states as follows:

In the plant, during the formation of pollen as the gametophytes, meiosis occurs and the respective pairs of homologous chromosomes segregate. Hence, when a hybrid cultivar is bred using a gametic fertility restorer gene and male-sterile cytoplasm, the hybrid anther exhibits a 1:1 segregation of pollen carrying the fertility restorer gene and pollen lacking the gene, resulting in a theoretical pollen fertility of 50%. The hybrid plant of the invention is characterized in that a) two or more copies of the fertility restorer gene are present, and b) these copies of the gene are located at two or more gene loci which do not have complete linkage relationship. It thus has the advantage that when pollen is formed by meiosis, there is a higher possibility that a gametic restorer gene will be present on one of the chromosomes.

Further, paragraph [0016] at page 8 of the present Specification provides a specific explanation of the mechanism by which the claimed hybrid plant has acquired higher fertility via description of the concrete, working examples.

The combined teachings of Brown, Hanson, Mariani, Schöffl, Mohanty, Akagi and Kazama taken alone or together do not teach or suggest the technical feature (*e.g.*, having two or more copies of a gametic fertility restorer gene at two or more gene loci, which do not have a complete linkage relationship) of the claimed invention nor the effect of this technical feature.

Difficulty in achieving the claimed invention

As discussed above, one of the most important features of the claimed invention is positioning/introducing multiple copies of a gametic fertility restorer gene at multiple gene loci. It is alleged in the Office Action that the claimed hybrid plant could readily have been achieved by one of ordinary skill in the art in view of the cited art teaching a fertility restoring plant line containing a homozygous fertility restorer gene and crossing said fertility restoring plant line

with a sterile plant line. Applicant respectfully disagrees with this allegation.

One of ordinary skill in the art at the time the invention was made could not have been assured of a successful outcome, even if he were to conceive of the idea of the claimed invention, despite the teachings of the cited art. The claimed invention was achieved only after the inventor established the following:

- 1) gametic fertility restorer genes introduced by genetic engineering function in the same way as intrinsic genes;
- 2) fertility can be restored even if the pollen has a single gametic fertility restorer gene; and
- 3) pollen having multiple copies of a gametic fertility restorer gene develops normally. (page 8, paragraph [0016] of the present Specification)

Further, the term "a fertility restorer gene" has been amended in the claims to read "a gametic fertility restorer gene." As explained above, this amendment to the claims is consistent with the findings described in the present Specification at page 8, paragraph [0016], and distinguishes the claimed invention over the teachings of the cited art.

Still further, it was only with great difficulty and effort that the inventor was able to successfully position multiple copies of a gametic fertility restorer gene in a plant at multiple gene loci, which do not have a complete linkage relationship. Precise experiments were carried out over a lengthy period of time and following an elaborate research plan (as described in Examples 1-6 of the present Specification) in order to achieve the claimed invention.

The Applicant respectfully calls the Examiner's attention to Example 6 and Figure 10 of the present Specification and the description in Example 6 of the production of "a 2-Loci Rf-1 Homozygous Fertile Restorer Line and a 3-Loci Rf-1 Homozygous Fertility Restorer Line." The fertility restorer line produced in Example 6 corresponds to the figure labeled "Fertility restorer line" under the heading "Breeding (present invention)" in Figure 10. Figure 10 illustrates an example of the claimed invention where two copies of a fertility restorer gene are located at each of two (*e.g.*, multiple) gene loci, which do not have a complete linkage relationship.

The fertility restorer line illustrated in Figure 10 is claimed in claim 9, and the specific procedure for producing the fertility restorer line is described in detail at, for example, pages 20-21, paragraphs [0042]-[0044].

Although Hanson is alleged to disclose a fertility restorer plant line containing a homozygous fertility restorer gene, one of ordinary skill in the art would recognize that the claimed hybrid plant could not have been obtained simply by crossing Hanson's plant line to a sterile plant line.

To attain the claimed hybrid plant, it was first necessary to produce a fertility restorer line containing multiple copies of a single fertility restorer gene at multiple gene loci. Further, it was necessary to cross this fertility restorer line with a sterile line, in order to produce the seed for a hybrid plant, and then to confirm that the hybrid plant was able to withstand cold conditions to confirm utility and effectiveness of the claimed invention. It took more than two years for the inventor to perform the series of experiments discussed above in accordance with an elaborate research plan that was detailed in advance with the aim of attempting to produce the claimed invention. It can therefore not be said those skilled in the art could have readily and successfully accomplished the claimed invention, simply in view of the teachings of the cited art.

Hanson does not teach multiple copies of a single fertility restorer gene at multiple gene loci

It is alleged in the Office Action that Hanson teaches the use of multiple copies of a fertility restorer gene as in the claimed invention. The Applicant respectfully disagrees.

At column 1, lines 51-54, Hanson states that "[f]ertility restorer genes that have been particularly useful for hybrid seed production are active as single dominant alleles at a locus, though multiple systems are sometimes used." One of ordinary skill in the art would understand this statement to mean that for breeding hybrid plants, fertility restorer genes that can function as a single dominant allele at a single locus are useful (such as Rf-1, the fertility restorer gene for rice BT-type cytoplasm male-sterility), but, there are some cases wherein multiple genes at multiple loci are required; such as is the case for fertility restoring QTL (quantitative trait loci) for the rice WA-type cytoplasm male-sterility). Those skilled in the art would understand that this information is irrelevant to the patentability of the claimed invention.

This is evidenced at column 8, lines 26-29 and column 72, lines 36-43 of the Hanson reference, which only teach that two distinct PPR motif containing genes lie in tandem in a *Petunia* RF locus. This is not the same as the claimed invention where multiple copies of a single fertility restorer gene are positioned/introduced at multiple gene loci.

At column 62, lines 30-31, Hanson states that "[t]he plant can have 2 or more copies of

the nucleic acid molecule." The sentence merely points out that the number of copies of the nucleic acid to be introduced is not limited to a single copy (col. 62, lines 22-31). There is no description or suggestion by Hanson of multiple copies of the same gene at multiple gene loci.

At column 78, lines 55-56, Hanson states that "[t]he third line is homozygous for one or more fertility restoration loci." Similar to the phrase in Column 1, lines 51-54, one of skill in the art would recognize this to mean that in some cases, multiple (distinct) genes at multiple loci are required to restore fertility, and therefore some fertility restoring lines contain distinct types of fertility restorer genes at multiple loci (col. 78, lines 47-61).

Consequently, there is no teaching or suggestion of the claimed invention by Hanson.

The cited art does not provide the correct sequence for the Rf-1 gene (SEQ ID NO: 49)

At page 11 of the Office Action, Akagi is relied on as teaching that "fertility is restored by the *Rf-1* gene." However, the sequence of the *Rf-1* gene had not been determined at the time that Akagi was published. Akagi merely teaches (at page 52) that "[t]he gene product of a nuclear-encoded gene, *Rf-1*, can rescue the CMS [cytoplasmic-male-sterile] character and nullify incompatibility between a CMS-cytoplasm and a nuclear genome carrying *Rf-1*. This trait was initially identified in Chinsurah Boro II, and was shown to be due to a single locus in the nuclear genome (Shinjo 1969). The function of *Rf-1* still remains unclear." Akagi is silent regarding the nucleotide sequence of the *Rf-1* gene and the amino acid sequence of the gene product of the *Rf-1* gene.

It is erroneously alleged at page 13 of the Office Action that Kazama "teach[es] the isolation of the rice *Rf-1* gene, which gametophytically restores fertility to male sterile rice plants comprising the BT cytoplasm." Applicant respectfully points out that this allegation can only be reached using hindsight.

Kazama describes a pentatricopeptide repeat-containing gene that promotes the processing of aberrant *atp6* RNA of cytoplasmic male-sterile rice. Kazama merely concludes that the sequence for the *PPR8-1* gene that he reports "is a possible candidate of *Rf-1*" (Abstract). Kazama notes at page 99 that "cloning of the *Rf-1* gene has not yet been reported." (This further supports that Akagi was not in possession of the sequences for the *Rf-1* gene and its gene product, as Kazama was published about nine years after Akagi.)

Furthermore, Kazama did not investigate the relationship between transgenic *PPR8-1* expression and restoration of fertility, but rather looked at the effect of the *PPR8-1* gene on *atp6* RNA processing in transgenic calli. Thus, at page 102, Kazama states that “[f]urther investigation of the fertility of the transgenic plants is needed in order to conclude that the *PPR8-1* gene is the *Rf-1* gene.”

It is also erroneously alleged in the Office Action that “[t]he *Rf-1* gene isolated by Kazama et al (May 2003) encodes a protein that is 100% identical to instant SEQ ID NO: 49 [sequence of the *Rf-1* gene product in the present application], as evidenced by Kazama et al (2005).” Kazama, in his 2003 article, teaches that the nucleotide sequence for *PPR8-1* appears in GenBank under the Accession No. AB106867. Kazama first submitted a version of the *PPR8-1* sequence on March 24, 2003 (*e.g.*, Acc. No. AB106867.1), which was first seen at NCBI on June 16, 2003. The Kazama article was published online on May 13, 2003. The *PPR8-1* sequence published June 16, 2003, with the Accession No. AB106867 had a predicted gene product of 791 amino acids and the sequence of the gene product differs from SEQ ID NO: 49 of the present application by four amino acid residues. The original *PPR8-1* sequence submitted to GenBank was subsequently replaced with a slightly different sequence August 18, 2003 (*e.g.*, Acc. No. AB106867.2), which has a predicted gene product that is identical to SEQ ID NO: 49.

Neither Akagi nor Kazama purport to possess the sequence of the gene or the sequence of the gene product responsible for restoring fertility to male-sterile rice. Kazama indicates that further investigation of the fertility of transgenic plants would be needed in order to conclude that the *PPR8-1* gene is the *Rf-1* gene. The other cited references do not teach SEQ ID NO: 49, as disclosed in the present application. The Akagi and Kazama references are also silent regarding the benefits of having multiple copies of the gene encoding the protein having an amino acid sequence of SEQ ID NO: 49 at multiple loci without a complete linkage relationship, as recited in the claims.

One of skill in the art would appreciate that very little precise information existed about fertility restorer genes before the making of the claimed invention, and accordingly, arriving at the claimed invention was all the more difficult.

Patentability of the plant according to claim 9

Claim 9 recites a "plant of fertility restoring line containing a gametic fertility restorer gene homozygously (*e.g.*, multiple copies of the gametic fertility restorer gene) at two or more loci." As explained above, the fertility restorer line according to claim 9 is illustrated in Figure 10 of the present Specification. This is clearly distinct from a fertility restoring line taught by the cited art, which contains a gametic fertility restorer gene at only a single locus. Paragraphs [0042]-[0043] at pages 20-21 of the present Specification describe production of the claimed fertility restorer line containing a single fertility restorer gene homozygously at two loci, and paragraph [0044] at page 21 describes the line with the fertility restorer gene homozygously at three loci. As discussed above, it was actually very difficult to obtain this fertility restoring line with multiple copies of the gene homozygously at multiple loci.

In view of the discussion above, Applicant respectfully requests that the rejections of claims 1-3 and 5-10 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell, Ph.D., Registration No. 48,025 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

Gerald M. Murphy, Jr.

Registration No.: 28977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road, Suite 100 East

P.O. Box 747

Falls Church, VA 22040-0747

703-205-8000